

**Mawyer, Denise T.**

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**From:** Walk, Roger A.  
**Sent:** Thursday, August 03, 2000 11:06 AM  
**To:** Putney, Rebecca M.  
**Subject:** Parexel suggestions on Biomarkers

Parexel suggestions

-----Original Message-----

**From:** Walk, Roger A.  
**Sent:** Friday, July 14, 2000 5:16 PM  
**To:** Kinser, Robin D.; Tricker, Anthony; 'islesail@rivnet.net'; Haussmann, Hans J.  
**Cc:** Solana, Rick P.  
**Subject:** FW: BIOMARKER STRATEGIES

It is interesting to see PAREXELS suggestions on biomarkers for the TES.

Could our 4 biomarker specialists (and their support - Rustemeier etc.) have a look at these suggestions and give me their opinion as to whether we should consider some of the suggestions for the Total Exposure Study some time early next week?

Have a nice weekend.  
Roger

-----Original Message-----

**From:** Stern, Warren [SMTP:Warren.Stern@parexel.com]  
**Sent:** Friday, July 14, 2000 2:15 PM  
**To:** 'ROGERWALK@YAHOO.com'  
**Cc:** Steuernagel, Carl; Roethig, Hans-Juergen  
**Subject:** BIOMARKER STRATEGIES

Dr. Roger Walk  
Director  
Worldwide Scientific Affairs  
Philip-Morris  
PO Box 2361  
Richmond, VA 23261

Dear Dr. Walk:

Parexel has recently concluded an alliance with a Massachusetts based company, MassTrace, which specializes in the use of biomarkers in human clinical trials. While their main orientation is the use of biomarkers in drug related clinical trials, the knowledge they have gained from many years of thinking and working on these issues, and, from the standpoint of selecting practical assays which provide noninvasive indices of enzymatic activity in patients or normal volunteers may be useful to Philip-Morris. Since MassTrace is bound by a secrecy agreement to Parexel, I took the liberty of seeking their expert opinion regarding the biomarker strategy for the smoking study being designed by Philip-Morris and collaborators. The comments and suggestions of the MassTrace biomarker experts are provided in the attachment.

If you would like to meet with their lead scientist, Dr. Alfred Ajami, to review the thoughts given in their proposal, or to discuss other matters relative to the biomarker strategy, we would be please to set up a meeting.

Best regards,

Warren Stern, PhD  
Sr. Vice President  
Scientific and Medical Services

cc: P. Leone, A. Ajami (MassTrace)  
C. Steuernagel

H-J. Roethig, MD